

## **Advisory Group for Data (AGD) – Meeting Minutes**

Thursday, 6th March 2025

09:00 – 16:10

*(Remote meeting via videoconference)*

<b>AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role:</b>
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Rachel Fernandez (RF)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Kirsty Irvine (KI)	AGD independent member (Chair)
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)
Tom Wright (TW)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman)) (not in attendance for part of items 5.1 and 5.2)
<b>NHS ENGLAND STAFF IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Garry Coleman (GC)	NHS England SIRO Representative (not in attendance for part of item 5.5)
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> items 5.1 and 5.2)
Andrew Ireland (AI)	Information Governance Specialist, IG Risk and Assurance, Privacy, Transparency, and Trust (PTT), Delivery Directorate ( <b>Observer:</b> items 8.1 and 8.2)
Jorge Marin (JM)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> item 5.7)

Harry Millard (HM)	Information Governance Officer, IG Risk and Assurance, Privacy, Transparency, and Trust (PTT), Delivery Directorate ( <b>Observer:</b> items 8.1 and 8.2)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Steph Rowley (SR)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> item 5.1)
Suzanne Shallcross (SS)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> items 5.2 and 5.3)
Simon Snowden (SS)	Senior Manager - specialist analytical support functions, Data Collection, Curation and Product, Data Product Development, Data and Analytics, Transformation Directorate ( <b>Presenter:</b> item 4.1)
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> items 5.5 and 5.6)
Emma Whale (EW)	Data Access and Partnerships, Data and Analytics, Transformation Directorate ( <b>Observer:</b> item 5.4)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
Sarah Woodhouse (SW)	Principal Consultant, NHS England Outcomes and Registries Programme (ORP) ( <b>Observer:</b> item 4.1)
<b>AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:</b>	
<b>Name:</b>	<b>Role / Area:</b>
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)

<b>1</b>	<b>Welcome and Introductions:</b> The AGD Chair welcomed attendees to the meeting.
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	<p>AGD noted that, due to unforeseen circumstances, only two AGD NHS England members were in attendance for part of items 5.1 and 5.2.</p> <p>Noting that the <a href="#">AGD Terms of Reference</a> state that “<i>The quorum for meetings of the Group or a Sub-Group is five members, including at least three independent members, one of whom may be the Chair, Deputy Chair or Acting Chair and <b>two of the three NHSE Members...</b></i>”, the Group agreed that, as there were two AGD NHS England members present, the meeting was still quorate for <b>all</b> agenda items and agreed to proceed on that basis.</p>
<b>2</b>	<p><b>Review of previous AGD minutes:</b></p> <p>The minutes of the AGD meeting on the 27<sup>th</sup> February 2025 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.</p>
<b>3</b>	<p><b>Declaration of interests:</b></p> <p>Claire Delaney-Pope noted a professional link to King's Health Partners (NIC-708913-Y2N1H-King's College Hospital NHS Foundation Trust) as part of her role at South London and Maudsley NHS Foundation Trust (SLAM). It was noted that SLAM was not part of this application, and that there were no financial arrangements between King's Health Partners and SLAM for this application. It was agreed that Claire would remain in the room, but would <b>not</b> be part of the discussion / or providing advice for this application.</p>
<b>4 BRIEFING PAPER(S) / DIRECTIONS:</b>	
<b>4.1</b>	<p><b>Title:</b> Medical Device Outcomes Registry (MDOR) National Joint Registry (NJR) Devices Data - Data Protection Impact Assessment (DPIA)</p> <p><b>Linked DPIAs:</b> This DPIA is linked to the MDOR National Vascular Registry (NVR) Devices Data DPIA that was discussed at AGD on the 27<sup>th</sup> March 2025.</p> <p><b>Presenter:</b> Simon Snowden</p> <p><b>Observer:</b> Sarah Woodhouse</p> <p>The purpose of the DPIA is in respect of the collection and analysis of a regular flow of implantable medical device data of patients in England from the NJR to NHS England's MDOR via Secure File Transfer Protocol. The flow is in relation to the MDOR being the national central means of collecting patient-level implantable device data to facilitate patient safety reviews of cross-registry data. Four core fields will flow from the NJR to MDOR, Organisation (ODS) Code, NHS Number, Operation Date and Unique Device Identifier.</p> <p>NHS England (NHSE) is required to process NJR medical devices data for the purposes of: <b>1)</b> developing and maintaining a central, patient identifiable database of all implantable medical devices received by a patient; <b>2)</b> enabling authorised healthcare professionals to access this central database to review all implants received by a patient under their care; and <b>3)</b> acting as a live, interoperable central linkage point across multiple clinical registries (both those within and outside of the</p>

	<p>Outcome Registry Platform) to facilitate timely patient safety reviews of cross-registry data as authorised by NHS England.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> <li>1. Does the DPIA adequately fulfil its purpose of identifying and reducing risks associated with the processing of personal data.</li> <li>2. Can AGD identify gaps in the DPIA that need to be addressed.</li> <li>3. Can AGD advise whether additional stakeholders should be consulted.</li> </ol> <p><b>Outcome of discussion:</b> AGD welcomed the draft DPIA and made the following observations / comments:</p> <p><b>4.1.1</b> AGD noted that the work outlined in the DPIA was impactful with a clear public interest.</p> <p><b>In response to points 1 and 2 above:</b></p> <p><b>4.1.2</b> AGD suggested that any restrictive statements in respect of Artificial Intelligence (AI) were reviewed and removed as may be necessary.</p> <p><b>In response to point 3:</b></p> <p><b>4.1.3</b> AGD suggested that the DPIA was updated to <b>1)</b> outline the consultation undertaken with data subjects; or <b>2)</b> clarify why no consultation with data subjects had taken place.</p> <p><b>4.1.4</b> AGD noted the NJR consent model and that not all recipients of implants would be included. Given the importance of clinical safety, AGD suggested other approaches be explored with relevant stakeholders to include all implant recipients for clinical safety purposes and that legislative changes were considered if necessary.</p> <p>AGD provided the following observations / comments separate to the advice requested:</p> <p><b>4.1.5</b> AGD noted that, notwithstanding the limited data that would be flowing, there is a risk of excessive processing of the data, for example, if MDOR only replicates existing NJR activities.</p> <p><b>4.1.6</b> AGD also suggested that the NJR transparency materials were reviewed, to ensure that it was explicitly clear that data would regularly flow to MDOR. There is also a risk that the data flow to MDOR is not in line with what patients were previously told would happen with their data.</p> <p><b>4.1.7</b> AGD suggested that in the interests of patient safety and choice, further consideration should be given by NHS England MDOR to routinely publishing a list of privately funded sector organisations that do / do not provide data, with an explanation of how publishing this information contributes to patient safety.</p>	
<p><b>5 EXTERNAL DATA DISSEMINATION REQUESTS:</b></p>		

5.1	<p><b>Reference Number:</b> NIC-774097-J9J0C-v0.3</p> <p><b>Applicant and Data Controller:</b> University College London (UCL)</p> <p><b>Application Title:</b> “MRC National Survey of Health and Development (NSHD) – tracing”</p> <p><b>Observers:</b> Suzanne Hartley and Steph Rowley</p> <p><b>Application:</b> This was a new application.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p><b>5.1.1</b> AGD noted that the s251 support covered the flow of mortality data, and advised that <b>1)</b> NHS England clarify that the Personal Demographics Service (PDS) dataset contains the most timely notification on deaths; <b>2)</b> if there is a dataset that would provide more timely death data, AGD advised that they would be supportive of this data flowing if there was a legal gateway to flow this data and a justification, in line with NHS England’s Data Access Service (DAS) <a href="#">standards</a>; and <b>3)</b> section 5(b) (Processing Activities) was updated to clarify the processing for removing deceased individuals from the mailout.</p> <p><b>5.1.2</b> AGD suggested that the application was updated throughout to reference the name of the third-party supplier.</p> <p><b>5.1.3</b> AGD suggested that the restrictive statement in section 5(b) “<i>The data will always remain on the servers at UCL</i>” was reviewed and updated as may be necessary to reflect the correct / factual information.</p> <p><b>5.1.4</b> AGD noted the information in the protocol (SD1.1) that states “...<i>study members who do not respond to the mail-out...add them to the ‘s251’ list</i>”; and suggested that NHS England advise the applicant that this information should also be included in the letter going out to cohort members, noting there is an ethical obligation to make individuals aware that their data will be obtained and processed if they do not reply, and that there is a legal basis for doing this.</p> <p><b>5.1.5</b> AGD noted and commended the applicant on the patient and public involvement and engagement (PPIE) undertaken to date.</p> <p><b>5.1.6</b> No AGD member noted a commercial aspect to the application.</p>	
5.2	<p><b>Reference Number:</b> NIC-688223-X1W4R-v0.8</p> <p><b>Applicant:</b> University of Nottingham</p> <p><b>Data Controllers:</b> University Hospitals of Derby and Burton NHS Foundation Trust</p>	

<p><b>Application Title:</b> “POSNOG - POSitive Sentinel NODe: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early-stage breast cancer who have metastases in one or two sentinel nodes”</p> <p><b>Observers:</b> Suzanne Shallcross and Suzanne Hartley</p> <p><b>Application:</b> This was a new application.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were supportive of the flow of data beyond five years after their recruitment for those cohort members consented on version four onwards <b>only</b>, and wished to draw to the attention of the SIRO the following substantive comments:</p> <p><b>5.2.1</b> AGD noted and agreed with the point in the NHS England Data Access Service (DAS) internal consent review document (SD5), that for those participants originally consented on versions one to three of the consent materials, it does <b>not</b> state that data would be collected beyond their anticipated five years of being actively involved in the study; whilst version four onwards of the consent material clearly outlines the intention to continue to use health records to check on participant health status.</p> <p><b>5.2.2</b> Whilst the Group agreed the value of the flow of data for all cohort members was high, and that cohort members would likely be supportive of this flow if asked, AGD felt there may be a consent issue that needed to be addressed. One AGD independent member thought that for those consented on versions one to three of the consent materials there was a barrier to further processing and that this section of the cohort should be reconsented; whilst the majority of AGD members thought the information was ambiguous and noted no restrictive statements to preclude further processing after five years.</p> <p><b>5.2.3</b> AGD suggested that the applicant could <b>1)</b> test expectations with a small selection of the cohort to see if they judged it to be within the consent they had given; <b>2)</b> the applicant review transparency materials shared with the cohort, i.e. newsletters, to clarify what participants were told; and <b>3)</b> the applicant should provide relevant evidence to NHS England based on the outcomes of both of these actions.</p> <p><b>5.2.4</b> Based on the outcome of these two actions, AGD suggested that the applicant may wish to consider <b>1)</b> seeking s251 support; <b>2)</b> reconsenting participants who consented on versions one to three of the consent materials.</p> <p><b>5.2.5</b> AGD confirmed that they were supportive of data flowing beyond five years after their recruitment for those cohort members consented on version four onwards</p>
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	<p>of the consent materials <b>only</b>, whilst the outstanding issues were resolved for those consented on versions one to three.</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p><b>5.2.6</b> Noting the points raised on the cohort / consent (points 5.2.1 to 5.2.5), AGD suggested that once this issue had been satisfactorily resolved, section 3(b) (Additional Data Access Requested) was updated with the date range for the data requested.</p> <p><b>5.2.7</b> AGD noted the reference in section 5 (Purpose / Methods / Outputs) to the data being “<i>pseudonymised</i>”, and noting that there was the ability re-identify individuals, and it was a consented cohort, suggested that this was reviewed / updated to reflect the correct / factual information.</p> <p><b>5.2.8</b> AGD queried the statement in section 5(a) (Objective for Processing) “...<i>to mandate this data request...</i>”; and suggested that this was reviewed and updated.</p> <p><b>5.2.9</b> AGD noted the statement in in section 5(b) that data will “...<i>not be linked with any other data</i>”; and suggested that this was reviewed / updated to reflect the correct / factual information.</p> <p><b>5.2.10</b> AGD queried the statement in section 5(b) (Processing Activities) that access is restricted to employees of “...<i>University Hospitals of Derby and Burton NHS Foundation Trust</i>”; and suggested that this was reviewed and either removed if incorrect; or that clarification was provided as to why the hospital employees need access to the data.</p> <p><b>5.2.11</b> The NHS England SIRO Representative queried whether death data was required, and was advised by NHS England that this data was available in the cancer datasets requested. AGD advised that if there was a dataset that would provide more timely or relevant death data, they would be supportive of this data flowing if this supported the research aims, if there was a legal gateway to flow this data and a justification, in line with NHS England’s Data Access Service (DAS) <a href="#">standards</a>.</p> <p><b>5.2.12</b> AGD noted that the research outlined appeared to provide the opportunity to produce worldwide benefits in respect of efficacy of this type of surgery, by either preventing unnecessary surgery, or providing assurance to those who have undergone surgery. It was therefore suggested that this was added to the start of section 5(d) (Benefits).</p> <p><b>5.2.13</b> The NHS England SIRO Representative asked that the applicant ensure that all public facing transparency materials were correct and aligned with the consent / transparency materials provided to the cohort, for example aligning the information on the website with the current patient information leaflet.</p> <p><b>5.2.14</b> No AGD member noted a commercial aspect to the application.</p>	
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5.3	<p><b>Reference Number:</b> NIC-708913-Y2N1H-v0.6</p> <p><b>Applicant and Data Controller:</b> King's College Hospital NHS Foundation Trust</p> <p><b>Application Title:</b> "King's College London Cardiovascular Diseases Database"</p> <p><b>Observer:</b> Suzanne Shallcross</p> <p><b>Application:</b> This was a new application.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> The majority of the Group were supportive of the application <b>if</b> the outstanding query on the roles of the parties was clarified. A minority of the Group (one member) was <b>not</b> supportive of the application <b>at this time</b> due to the outstanding query on the roles of the parties.</p> <p>The Group wished to draw to the attention of the SIRO the following substantive comments:</p> <p><b>5.3.1</b> AGD noted that prior to the meeting, a query had been raised by an AGD independent member, in respect of why the 'King's College London (KCL) Cardiovascular Diseases Database' (KCL-CVD) bears the name of KCL, when they are <b>not</b> listed as a Data Controller or as a Data Processor in the application. AGD were advised by NHS England's Data Access Service (DAS) that this had been discussed with the applicant prior to the meeting, and that confirmation had been received that KCL had <b>no</b> involvement with the database.</p> <p><b>5.3.2</b> AGD noted the response from the applicant, and expressed concern that a database was being created using the KCL name, when KCL as a legal entity have no involvement. It was suggested that <b>1</b>) the applicant seek the views of the KCL Data Protection Officer (DPO); and <b>2</b> the applicant clarifies that KCL will <b>not</b> be named in any publications resulting from the work outlined in this application.</p> <p><b>5.3.3</b> The AGD independent Specialist Ethics Adviser noted concern that the impression was incorrectly being given that KCL was involved with, or had some responsibility for, KCL-CVD, and that this raised both ethical and UK General Data Protection Regulation (UK GDPR) issues.</p> <p><b>5.3.4</b> AGD noted that prior to the meeting, a query had been raised by an AGD independent member, in respect of, the statement in section 5(b) (Processing Activities) that <i>"The Data will be accessed onsite at the premises of KCL only"</i>, and whether the data would be stored on King's College Hospital NHS Foundation Trust (KCH) servers or on KCL servers. It was noted by the Group that it would <b>not</b> be possible for data to be stored at KCL if they were not a Data Controller or a Data Processor; and suggested that the application was updated to reflect the correct /</p>	
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factual information, in line with [NHS England DAS Standard for Data Controllers](#) and [NHS England DAS Standard for Data Processors](#).

**5.3.5** In addition, AGD noted that the public facing transparency materials stated that the data would be stored at KCH; and suggested that references were reviewed and the application updated to reflect the correct / factual information.

**5.3.6** AGD noted that KCL academics could access the data via an honorary contract with KCH or Guy's and St Thomas' NHS Foundation Trust; and noted that this raised further queries on the role of KCL, and whether they are involved in a more substantive manner, noting no other academics will get the same preferential treatment.

**5.3.7** AGD noted references in section 5 (Purpose / Methods / Outputs) to *“researchers from the KCL-CVD”*; and noting that KCL-CVD is not a legal entity, suggested that this was reviewed and the application updated to reflect the correct / factual information.

**5.3.8** AGD suggested that NHS England satisfy themselves that **all** the individuals accessing, processing and / or analysing the data are covered by the relevant Data Security and Protection Toolkits (DSPTs), and that the application was updated as may be appropriate.

In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:

**5.3.9** In respect of the patient information materials provided, AGD suggested that **1)** the reference to the database being stored for *“ten years”* is reviewed, noting this may cause ethical or transparency issues in the future should it be determined that the database would continue to be useful for more than ten years; **2)** the potentially restrictive information outlining who will see the data is reviewed and updated / futureproofed as may be necessary; **3)** the information outlining the NHS England datasets listed are reviewed and updated to be less restrictive if new/other datasets might be requested in the future; and **4)** NHS England to discuss the CogStack logo on the patient information materials with the applicant, to clarify why this is being used and their role with KCL-CVD.

**5.3.10** AGD provided advice on how the scope of the purpose is documented in respect of Artificial Intelligence (AI) and **1)** highlighted the need to be transparent and clear in the application where AI is being used and in what context; and **2)** suggested that NHS England review the application to ensure there are the relevant contractual protections, noting the potential wide use of NHS England data in terms of the AI tools within the KCL-CVD.

**5.3.11** AGD noted the information provided in the KCL-CVD Oversight Committee Terms of Reference (SD5); and suggested that this could be updated to also include an assessment of the balance between public and commercial benefit, in line with

	<p>National Data Guardian (NDG) <a href="#">guidance on benefits</a>. However, AGD noted the agreement may need amendments to allow commercial use.</p> <p><b>5.3.12</b> The NHS England SIRO Representative noted the concerns raised by the Group and stated that this application does <b>not</b> proceed further without a further discussion.</p> <p><b>5.3.13</b> AGD members noted that it was not clear whether was a commercial aspect to the application.</p>	SIRO Rep / DAS
<b>5.4</b>	<p><b>Reference Number:</b> NIC-755603-Q8Y4Y-v0.6</p> <p><b>Applicant and Data Controller:</b> Keele University</p> <p><b>Application Title:</b> “MIDAS (MIDAS-GP and MIDAS-Population) project”</p> <p><b>Observer:</b> Emma Whale</p> <p><b>Application:</b> This was a new application.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p><b>5.4.1</b> AGD noted in the NHS England Data Access Service (DAS) internal application assessment form, that the Chief Investigator (CI), who was previously employed by Keele University is now employed by Sheffield Hallam University, and holds an honorary contract with Keele University. Noting that Sheffield Hallam University are <b>not</b> named in the application, the Group suggested that in line with <a href="#">NHS England’s DAS Standard for Honorary Contracts</a> and <a href="#">NHS England DAS Standard for Data Controllers</a> NHS England clarify with the applicant that <b>1)</b> Sheffield Hallam University would <b>not</b> be credited on any academic outputs <b>2)</b> what the supervision arrangements are for the CI; <b>3)</b> who will sign the data sharing agreement, noting this cannot be the CI; and <b>4)</b> how access to the data will be restricted to employees of Keele University who have authorisation from the CI, as noted in section 5(b) (Processing Activities).</p> <p><b>5.4.2</b> AGD noted and commended NHS England’s DAS on the internal consent review undertaken, and agreed that there was a legal gateway in consent to flow the identifying data. AGD supported the suggestion in the consent review, that additional steps could be taken by the applicant to improve transparency, and suggested that NHS England’s DAS discuss this further with the applicant.</p> <p><b>5.4.3</b> AGD noted the various time limits within the consent and transparency materials, and whilst not relevant to his iteration of the application, highlighted this for the applicant and NHS England to be aware of.</p>	

	<p><b>5.4.4</b> AGD suggested that section 3(c) (Patient Objections) was updated to correctly reflect that National Data Opt-outs will <b>not</b> be applied.</p> <p><b>5.4.5</b> AGD suggested that the application was updated to clarify why the identifiers are being held, if there will be no attempt to re-identify.</p> <p><b>5.4.6</b> It was the view of AGD that there was <b>no</b> commercial aspect to the application.</p>	
<b>5.5</b>	<p><b>Reference Number:</b> NIC-402963-P0Y5D-v3.8</p> <p><b>Applicant:</b> University of Liverpool</p> <p><b>Data Controller:</b> University of Oxford</p> <p><b>Application Title:</b> "ISARIC4C (ISARIC Coronavirus Clinical Characterisation Consortium) - Clinical Characterisation Protocol (CCP-UK)"</p> <p><b>Observer:</b> Jodie Taylor-Brown</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 13<sup>th</sup> January 2022, 23<sup>rd</sup> September 2021, 22<sup>nd</sup> October 2020 and the 24<sup>th</sup> September 2020.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meeting on the 22<sup>nd</sup> September 2020.</p> <p>The application and relevant supporting documents were previously presented / discussed at the General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) meetings on the 15<sup>th</sup> September 2021 (<i>Notes from this meeting were published in the 23/09/2021 IGARD meeting minutes</i>); and the 23<sup>rd</sup> September 2020 (<i>Notes from this meeting were published in the 24<sup>th</sup> September 2020 IGARD meeting minutes</i>).</p> <p><b>Application:</b> This was an amendment application.</p> <p>NHS England were seeking general advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were <b>not</b> supportive of the application <b>at this time</b> and wished to draw to the attention of the SIRO the following significant comments, and suggested that the application be brought back to a future meeting:</p> <p>AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents.</p> <p><b>5.5.1</b> AGD noted the information in the NHS England Data Access Service (DAS) internal Escalation Form in respect of the legal basis for the processing / flow of data, and the questions raised with the applicant. The Group noted that whilst there may be a case to be made for some aspects of the proposed processing to be carried out under Regulation 3 of The Health Service (Control of Patient Information)</p>	

<p>(COPI) Regulations 2002, there were issues with the information in the public facing transparency materials, where Regulation 5 was cited, and confirmation that the National Data Opt-out (NDO) would be applied (noting that it would <b>not</b> usually be applied under Regulation 3).</p> <p><b>5.5.2</b> The Group noted that throughout the application, both the language used, i.e. “<i>research</i>”, and the nature of some of the activities described, aligned with Regulation 5, not Regulation 3 put forward as the legal basis for this application.</p> <p><b>5.5.3</b> The Group suggested that if the applicant wanted to make a case that the application / aspects of the application align with Regulation 3, then the applicant should <b>1)</b> update section 5(a) (Objective for Processing) to clarify the specific limb(s) of Regulation 3 that each activity / dataset would align with; <b>2)</b> review / update the outputs in section 5(c) (Specific Outputs Expected) and benefits in section 5(d) (Benefits) to align with each Regulation 3 activity in section 5(a) in line with <a href="#">NHS England DAS Standard for Expected Outcomes</a> and <a href="#">NHS England DAS Standard for Expected Measurable Benefits</a>; <b>3)</b> review and update the transparency materials as may be necessary, to clarify the change in legal basis and explain why the position on applying the NDO had changed (noting that there are occasions where the NDO has been applied where Regulation 3 has been cited due to policy reasons); and <b>4)</b> clarify the number of local opt-outs applied since the current transparency had been published.</p> <p><b>5.5.4 ACTION: Separate to this application and for NHS England to consider:</b> AGD noted that NHS England’s Data &amp; Analytics had confirmed in November 2024 in relation to a previously closed COPI Regulation 3 action (Action Ref: AGD0178) that they were to set up a register for every time Regulation 3 is used, and suggested that the AGD Caldicott Guardian Team Representative and NHS England Data and Analytics Representative clarify NHS England’s existing Regulation 3 record keeping / sign-off mechanism with NHS England’s Privacy, Transparency and Trust (PTT),</p> <p>In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review:</p> <p><b>5.5.5</b> AGD suggested that given the significant volume of data flowing and the nature / sensitivity of the data flowing, e.g. HIV status, this would require a Data Protection Impact Assessment (DPIA); and suggested that NHS England discuss this further with the applicant, in line with the Information Commissioner’s Office (ICO) <a href="#">guidance</a> on DPIAs.</p> <p><b>5.5.6</b> Noting the multiple Data Processors outlined in section 1(c) (Data Processor(s)), AGD queried if this was reflective of the facts, noting the reference to some of the Data Processors formulating research questions. AGD suggested that applicant clarified how the parties were allocated the Data Controller / Data Processor roles in line with the UK General Data Protection Regulation (UK GDPR)</p>	<p>CG Rep / D&amp;A Rep</p>
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	<p>and the <a href="#">NHS England DARS Standard for Data Controllers</a> and <a href="#">NHS England DARS Standard for Data Processors</a>, and borne of the facts.</p> <p><b>5.5.7</b> The AGD Caldicott Guardian Team Representative expressed concern on the practicalities of ensuring that, as noted in the application, General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR) data would be used for COVID-19 purpose <b>only</b>; and suggested that NHS England discuss this further with the applicant.</p> <p><b>5.5.8</b> AGD noted the reference in section 5(b) (Processing Activities) to the data being linked with data obtained from the UK Health Security Agency (UKHSA); and suggested that NHS England satisfy itself that this was in line with the legal basis and the data processing agreement in place with UKHSA.</p> <p><b>5.5.9</b> AGD noted the statement in section 5(b) <i>“Once the researcher has completed their research, both parties will delete the individual project data folder”</i>; and suggested that this was reviewed / updated, noting that data may need to be retained for audit purposes.</p> <p><b>5.5.10</b> AGD noted references in the application to <i>“anonymised”</i> datasets; and suggested that these were reviewed / updated where relevant to refer to <i>“pseudonymised”</i>.</p> <p><b>5.5.11</b> Notwithstanding the suggested amendments already outlined (see point 5.5.4), AGD suggested that <b>1)</b> section 5(c) and section 5(d) were reviewed / updated to ensure that the outputs and benefits were still relevant noting the research had been ongoing for some time, in line with in line with <a href="#">NHS England DAS Standard for Expected Outcomes</a> and <a href="#">NHS England DAS Standard for Expected Measurable Benefits</a>; and <b>2)</b> any reference to a journal was updated to specifically name the journal.</p> <p><b>5.5.12</b> No AGD member noted a commercial aspect to the application.</p>	
<b>5.6</b>	<p><b>Reference Number:</b> NIC-660630-L4H3T-v4.3</p> <p><b>Applicant and Data Controller:</b> Digital Health and Care Wales</p> <p><b>Application Title:</b> “Identifiable data required for DHCW's Statutory Functions”</p> <p><b>Observer:</b> Jodie Taylor-Brown</p> <p><b>Previous Reviews:</b> The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 2<sup>nd</sup> November 2023.</p> <p><b>Linked applications:</b> This application is linked to <b>NIC-314399-K4J9S</b> (<i>which has now been superseded by NIC-660630-L4H3T</i>).</p> <p><b>Application:</b> This was an amendment application.</p> <p>NHS England were seeking general advice on the application.</p>	

	<p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents.</p> <p><b>5.6.1</b> AGD noted the inconsistency between the UK General Data Protection Regulation (UK GDPR) when using an English or Welsh Direction, and were provided a verbal update by the NHS England SIRO Representative as to why there was a difference in approach, i.e. that the Welsh Direction is used to request a service. AGD queried if the Welsh Directions could be relied on to satisfy the Common Law Duty of Confidentiality as per the English Directions, and suggested that NHS England clarify this with NHS England's Privacy, Transparency and Trust (PTT) if this had not already been confirmed.</p> <p><b>5.6.2</b> AGD noted that opt-outs would <b>not</b> be applied, due to the data being requested under a Welsh Direction, and not because it was direct care.</p> <p><b>5.6.3</b> AGD suggested that the applicant's privacy notice was reviewed / updated to ensure that it was clear on the proposed processing in line with UK GDPR.</p> <p><b>5.6.4</b> AGD noted that it was unclear if <b>only</b> substantive employees of Digital Health and Care Wales would access the data for non-direct care purposes; and suggested that the application was updated with clarification.</p> <p><b>5.6.5</b> AGD suggested that the data retention date in section 8(a) (Data Retention) was updated to align with the end date of the application.</p> <p><b>5.6.6</b> AGD noted the reference in section 5(c) (Specific Outputs Expected) to "<i>expensive patients</i>"; and suggested that this was updated to use a more sensitive term.</p> <p><b>5.6.7</b> No AGD member noted a commercial aspect to the application.</p>	
<b>5.7</b>	<p><b>Reference Number:</b> NIC-709342-K9Z8V-v0.5</p> <p><b>Applicant:</b> Queen Mary University of London (QMUL)</p> <p><b>Data Controller:</b> Queen Mary University of London and University College London</p> <p><b>Application Title:</b> "Prostate cancer treatment patterns and outcomes by ethnicity: a national cohort study using routinely collected data"</p> <p><b>Observer:</b> Jorge Marin</p> <p><b>Application:</b> This was a new application.</p> <p>NHS England were seeking general advice on the application.</p>	



	<p>Should an application be approved by NHS England, further details would be made available within the <a href="#">Data Uses Register</a>.</p> <p><b>Outcome of discussion:</b> AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p><b>5.7.1</b> AGD noted in section 5(a) (Objective for Processing) that exclusions would be applied by QMUL when analysing the data in NHS England's Secure Data Environment (SDE); and to clarify why this data minimisation could not be carried out by NHS England.</p> <p><b>5.7.2</b> AGD noted that in addition to the data sharing agreement (DSA), there was also a 'User Agreement' for those individuals accessing data in NHS England's SDE, that covers off key points, including, but not limited to, specific user access and restrictions on exporting data; and suggested that this was referred to in section 5(b) (Processing Activities) of the application.</p> <p><b>5.7.3</b> AGD suggested that section 3(b) (Additional Data Access Requested) was updated to remove reference to the data being provided as a data "<i>extract</i>" and to correctly reference the data being accessed in NHS England's SDE.</p> <p><b>5.7.4</b> AGD noted reference to the applicant accessing the 'electronic Prescribing and Medicines Administration' dataset (ePMA); and suggesting that this was either removed if incorrect, or added to section 3(b) and an appropriate justification of how this will be used in section 5(a), in line with <a href="#">NHS England DAS Standard for Objective for Processing</a>.</p> <p><b>5.7.5</b> AGD noted the potential shortcoming of the ethnicity fields in the National Disease Registration Service (NDRS) dataset; and suggested that NHS England ensure that the applicant is aware of this; and ensures that this is reflected in any outputs and / or recommendations from the research.</p> <p><b>5.7.6 ACTION: Separate to this application and for NHS England to consider:</b> The AGD NHS England Caldicott Guardian Team Representative reiterated a point from the 28<sup>th</sup> November 2024 and the 17th October 2024, that research using datasets with incomplete ethnicity data may introduce bias into the results; and advised that further discussions would be held internally on this point to discuss possible solutions, such as a dedicated dataset. AGD noted that they were supportive of this, noting that this was an issue they had discussed previously.</p> <p><b>5.7.7</b> The NHS England SIRO Representative noted that QMUL had a number of Data Security and Protection Toolkits (DSPTs); and suggested that NHS England satisfy themselves that <b>all</b> the individuals accessing, processing and / or analysing the data are covered by the relevant DSPTs, and that the application was updated as may be appropriate.</p> <p><b>5.7.8</b> AGD noted and commended the applicant on the patient and public involvement and engagement (PPIE) throughout the duration of the project to date.</p>	<p>CG Rep</p>
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	<b>5.7.9</b> It was the view of AGD that there was <b>no</b> commercial aspect to the application.	
<b>6 INTERNAL DATA DISSEMINATION REQUESTS:</b>		
<i>There were no items discussed</i>		
<b>7 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL</b>		
<i>There were no items discussed</i>		
<b>8 OVERSIGHT AND ASSURANCE</b>		
<b>8.1</b>	<p><b>Oversight and Assurance Process</b></p> <p><b>Workstream 1 – Precedent approved internal and external applications</b></p> <p>The <a href="#">Statutory Guidance</a> states that the data advisory group (AGD) should be able to provide NHS England with advice on: “<i>Precedents for internal and external access, including advising in accordance with an agreed audit framework whether processes for the use of precedents are operating appropriately, to provide ongoing assurance of access processes</i>”.</p> <p>In advance of the meeting, the AGD independent members were provided with <b>1)</b> two applications (selected by the AGD Secretariat); <b>2)</b> internal application assessment forms for each of the two applications; and <b>3)</b> an oversight and assurance template to complete.</p> <p>Following review of the applications by the AGD independent members <b>out of committee</b>, the completed oversight and assurance templates were sent to the AGD Secretariat prior to the meeting.</p> <p>It was noted that only <b>high-level points</b> would be discussed in meeting (and noted in the minutes); however, the full suite of comments and feedback from AGD independent members on the oversight and assurance templates would be collated by the AGD Secretariat and shared with the NHS England SIRO representative and relevant NHS England colleagues as may be appropriate.</p> <p>Please see <b>appendix A</b> for high-level points raised in-meeting on the two applications.</p>	
<b>8.2</b>	<p><b>Oversight and Assurance Conclusion / Review</b></p> <p>AGD and the NHS England SIRO Representative reiterated points raised at previous AGD meetings that for applications reviewed as part of oversight and assurance, there were no documents available that provided an audit trail outlining how the decision had been reached to progress the application down the NHS England precedent route. In addition, AGD asked that all documentation, where a decision is made, is clearly dated noting information was available in the notes section of the</p>	

	<p>customer relationship management (CRM) system (which Independent Members do not have access to), however the documentation should also be date stamped.</p> <p><b>ACTION:</b> The AGD NHS England Data and Analytics Representative to ensure that all relevant documentation was uploaded to the CRM system as agreed previously and for audit purposes, and that any documentation uploaded contained a clearly dated audit trail of how the decision to progress the application down the NHS England precedent route had been undertaken.</p> <p>AGD reiterated a number of points previously raised at AGD meetings as part of oversight and assurance including, but not limited to: provide a copy of the knowledge base or the text relating to the reusable decision in the abstract of the application or SDA; that the abstract or SDA clearly identify which documents had been used by the decision maker to make the decision to progress an application down the NHS England precedent route; and to ensure that all decisions made are date stamped on the relevant documentation, for example the SDA, which NHS England state is a working document.</p> <p><b>ACTION:</b> for the AGD NHS England Data and Analytics Representative to feed back to NHS England that the knowledge base be provided to AGD; the SDA/abstract clearly articulate what documents had been reviewed to make the decision; and all documents are date stamped and up to date.</p> <p>The AGD Secretariat Manager noted that a new workstream was due to start at the end of March: <b>Workstream 2 - Internal and external applications that have had an independent review and been approved internally</b> (in the last 6 months). This would be a monthly task and would be looking at those applications which had not been supported, majority / minority supported, deferred or offering advice only, where NHS England had made the decision to flow the data, and the application had not come back to AGD via the SIRO precedent route. The first round of oversight and assurance for this workstream would capture all applications flagged from 1<sup>st</sup> April 2024 to December 2024.</p> <p><b>ACTION:</b> The AGD Secretariat to add workstream 2 to the 27<sup>th</sup> March 2025 AGD meeting.</p>	<p>D&amp;A Rep</p> <p>D&amp;A Rep</p> <p>AGD Sec</p>
<b>9 AGD OPERATIONS</b>		
<b>9.1</b>	<p><b>Risk Management Framework</b></p> <p>AGD has been previously informed that a risk management framework is being developed by Data Access and had commented on early thinking about such a Framework. Nonetheless, presently AGD were still operating using the precedent and standard framework as an interim arrangement since February 2023 and AGD were concerned that the permanent Risk Management Framework was not in place. The Group discussed the NHS England corporate risk management framework (see minutes of 14<sup>th</sup> November 2024) and the AGD chair subsequently formally asked via email if the NHS England corporate risk management framework could be used. The</p>	

	<p>NHS England SIRO Representative updated the Group that NHS England was still considering the request, including how the NHS England corporate risk management framework could be adapted for AGD.</p> <p><b>ACTION:</b> The NHS England SIRO Representative advised that an update would be provided at next week’s meeting.</p>	SIRO Rep
9.2	<p><b>Standard Operating Procedures (SOPs) (Update from Vicki Williams)</b></p> <p>The ongoing forward plan of work for creating the AGD Standard Operating Procedures was discussed.</p> <p>The Group noted that the ‘AGD member Declaration of Interest’ was in the process of being finalised, and a further update on this would be provided in due course, and published on the AGD webpage.</p>	
9.3	<p><b>AGD Stakeholder Engagement</b></p> <p><i>There were no items discussed</i></p>	
9.4	<p><b>AGD Project Work</b></p> <p><i>There were no items discussed</i></p>	
10 Any Other Business		
10.1	<p><b>AGD recruitment (Update from Vicki Williams)</b></p> <p>The AGD Secretariat Manager advised the Group that the job adverts for the AGD independent member roles were now live; and that the adverts / job descriptions had been circulated to a large number of key stakeholders.</p> <p>Further information can be found on the <a href="#">AGD recruitment webpage</a> and the <a href="#">NHS England’s working for us webpage</a>.</p> <p>The five adverts and job descriptions can be found here:</p> <ul style="list-style-type: none"><li>• AGD Chair <a href="#">NHS England » Working for us - AGD Chair</a></li><li>• AGD Lay Member <a href="#">NHS England » Working for us - AGD Lay Member</a></li><li>• AGD Specialist Clinician <a href="#">NHS England » Working for us - AGD Clinician Member</a></li><li>• AGD Specialist Adult Social Care <a href="#">NHS England » Working for us - AGD Adult Social Care Member</a></li><li>• AGD Specialist Academic / Research <a href="#">NHS England » Working for us - AGD Academic / Research Member</a></li></ul> <p>The deadline for applications is <b>midnight on Sunday, 23<sup>rd</sup> March 2025</b>.</p> <p>The Group noted and thanked Vicki for the verbal update and the work done to date on this.</p>	

10.2	<p><b>Datasets / Data Fields</b></p> <p>As part of the discussion of the applications at today's meeting, AGD raised a number of queries on what data fields are available in each dataset; and it was agreed by the Group, that as part of AGD's learning and development, there would be ongoing update, led by the AGD Data and Analytics Representative, to provide the Group with further details on this, which will further support the AGD review of applications.</p> <p><b>ACTION:</b> AGD Secretariat to add 'datasets / data fields learning and development update' to the AGD internal forward plan.</p> <p><b>ACTION:</b> AGD Data and Analytics Representative to liaise with the relevant colleagues(s) in Data and Analytics, to discuss the information required by AGD; and to update the AGD Secretariat on the appropriate colleague to liaise with to agree a meeting date to attend.</p>	AGD Sec D&A Rep
10.3	<p><b>NHS DigiTrials Specific Opt-out (Presenter: Tom Wright)</b></p> <p>AGD were provided with a verbal update on the ongoing work within NHS DigiTrials in respect of DigiTrials project specific opt-outs. The NHS England SIRO Representative advised the Group that he would be having further discussions on this with NHS England DigiTrials following the update in-meeting.</p> <p>AGD noted and thanked Tom for the verbal update provide; and advised that they welcome a briefing paper / discussion at a future AGD meeting as soon as possible.</p> <p><b>ACTION:</b> AGD Secretariat to add 'NHS England DigiTrials Specific Opt-out' to the AGD internal forward plan.</p>	AGD Sec
10.4	<p><b>Opt-out public deliberation</b></p> <p>Paul Affleck noted that following the AGD meeting on the 30<sup>th</sup> January 2025, where Opt-out public deliberation was discussed; he attended one of the events as an observer, as opposed to representing AGD.</p>	
10.5	<p><b>National Data Day</b></p> <p>The AGD Chair noted that UseMyData are organising a conference to mark National Patient Data Day on 24<sup>th</sup> June 2025 in Leeds, with speakers including Dr Nicola Byrne (National Data Guardian) and Ming Tang (Chief Data and Analytics Officer, NHS England), and queried if this was something that the NHS England Deputy SIRO / SIRO Representative were aware of, and – given the focus of the conference - whether AGD members, who were geographically close to Leeds, should attend either in an individual capacity or be invited be invited to represent AGD.</p> <p><b>ACTION:</b> the NHSE England SIRO Representative to review the event and come back to a future AGD meeting.</p>	SIRO Rep

**Meeting Closure**

As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.

## Appendix A

### Oversight and Assurance Review: workstream 1 – 6<sup>th</sup> March 2025

Ref:	NIC Number:	Organisation:	Areas to consider:
250306a	NIC-148267-W26RZ-v7.2	University of Oxford	<ul style="list-style-type: none"> <li>The Group noted that the application had last been seen by AGD on the 2<sup>nd</sup> May 2024 under oversight and assurance when AGD had <b>not</b> supported the application and raised significant concerns. The application had not come back to AGD nor progressed via the SIRO precedent. No assessment provided advising why this was suitable for the precedent route, therefore unclear if the precedent was applied correctly.  <b>Process point: Action for D&amp;A Representative</b> to ensure that it is clear in s1 of the DSA or in the SDa what documents were reviewed to make the decision with regard to the precedent route.</li> <li>AGD noted that moving forward a new monthly oversight and assurance workstream 2 had been set up: <b>Internal and external applications that have had an independent review and been approved internally</b> (in the last 6 months)</li> <li>AGD asked the NHSE SIRO Representative to consider whether all applications should have an</li> </ul>

			<p>independent review after a certain number of years.</p> <p><b>Action for the SIRO Rep:</b> to consider whether all applications should have an independent review.</p> <ul style="list-style-type: none"> <li>The Group requested that should this application be extended beyond December 2025, that it be brought back to AGD for a full independent review.</li> </ul>
250306b	NIC-389134-S8L1C-v16.2	University of Oxford	<ul style="list-style-type: none"> <li>The Group noted that the application had last been seen by AGD on the 9<sup>th</sup> November 2023 when AGD had been supportive of the extension and renewal, but had <b>not</b> been supportive of the amendments until the substantive comments had been met. The application had not come back to AGD nor progressed via the SIRO precedent, and with no audit trail of the decision made by NHSE, it was unclear why this application was suitable for the present route. <ul style="list-style-type: none"> <li><b>Process point: Action for D&amp;A Representative</b> to ensure that it is clear in s1 of the DSA or in the SDa what documents were reviewed to make the decision with regard to the precedent route.</li> </ul> </li> <li>AGD noted that moving forward a new monthly oversight and assurance workstream 2 had been set up: <b>Internal and external applications that</b></li> </ul>



			<p><b>have had an independent review and been approved internally</b> (in the last 6 months)</p> <ul style="list-style-type: none"> <li>• To provide a copy of the knowledge base or the text relating to the reusable decision in the abstract / SDa. <ul style="list-style-type: none"> <li>○ <b>Action for the D&amp;A Representative:</b> to provide a copy of the knowledge base referenced, or for the wording of the knowledge base cited to be included in the SDa.</li> </ul> </li> <li>• It was unclear which NHSE standards had been applied. <ul style="list-style-type: none"> <li>○ <b>Process point: Action for D&amp;A Representative</b> to ensure that is clear in the SDA / escalation form, as an audit trail, which NHSE standards have been applied.</li> </ul> </li> </ul>
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